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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,241	02/07/2002	Masahide Sato	219196US0	6563

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,241

Applicant(s)

SATO ET AL.

Examiner

Sally A. Sakelaris

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 8 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Species I, a pair of primers including SEQ ID NOS: 7 and 8, and methods employing that pair of primers for examination. Claims 1-4, 7, and 8 read on the elected species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Priority

Acknowledgement of claim to foreign priority of Japanese Application, 2001034113, filed 2/9/2001 under 35 U.S.C. 119(a)-(d) has been made, however applicant should note that the translation of this foreign priority document has not yet been received and as a result the claim to foreign priority under the same has not yet been granted.

Information Disclosure Statement

The information disclosure statements filed April 15, 2002 and March 3, 2004 both fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

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It should be noted that only the English abstracts of the Japanese patent documents listed on both of the IDSs have been considered, not the entire, un-translated Japanese patents.

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8's recitation of such expansive limitations(i.e., "primers have one or more base substitutions, deletions, or insertions") does not at all further limit the primers of SEQ ID NO:7 and 8, instead it is much broader.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-4, 7, and 8 are indefinite over the recitation of "the linker portion". The phrase lacks antecedent basis as claim 1 recites "the linker portion" but makes no prior reference to a sequence or gene to which "the linker portion" refers. It is therefore unclear which sequence is identified by the linker portion and appropriate correction is required.

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B. Claims 1-4, 7, and 8 are indefinite over the recitation of “which includes the base sequences listed as SEQ ID NOS: 1-6”. It is unclear what, exactly, includes these sequences. It is unclear whether it is the “N-terminal end of yeast gene Lg-FLO1” that is to include SEQ ID NOS 1-6, a portion of yeast chromosome IX that is to include SEQ ID NOS: 1-6, or even base sequences (A), (B), or (C) that are intended to include SEQ ID NOS:1-6. Applicant should amend the claim to clarify what sequence, or part of what sequence, is required to include SEQ ID NOS:1-6.

C. Claims 7 and 8 are indefinite over the recitation of “respectively the base sequences listed as SEQ ID NO:7 and NO:8: as it is unclear if both SEQ ID NOS: 7 and 8 are required in the same set, or if they are each in different sets, considering applicant’s recitation of “respectively”. Applicant should amend the claim so that their intended requirement for the inclusion of both primers in the same set is clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The specification discloses SEQ ID NOS:1-6 which correspond to 3,657 bp of the left telomere end of yeast(*S. cerevisiae*) chromosome IX while SEQ ID NO: 7 corresponds to 20 bp of the Lg-Flo1 gene of chromosome I and SEQ ID NO: 8 corresponds to 20 bp of the left telomere end of chromosome IX. Claims 1-4, 7, and 8 are directed to encompass a primer capable of amplifying an undefined linker portion between a sequence (A) and a sequence (B) comprising a portion of yeast chromosome IX linked downstream from said base sequence (A) comprising a portion of the N-terminal end of yeast gene Lg-FLO1, and which includes SEQ ID NOS: 1-6. The minimal structural requirements such as "between", "portion", and the use of open language such as "comprising" encompasses a large genus of possible sequences and structures. However, the specification does not adequately describe this genus. For example, there is no structure described for the primers, as the claim is inclusive of "portions" which can be read as comprising any at least 2 bp, that are anywhere between base sequence (A) and (B). In addition, no structural details of the primer are conveyed in its being "capable of amplifying the linker portion". There exists a myriad number of oligonucleotides with a free 3' hydroxyl group that could amplify the linker portion. A very large genus of structures are claimed in applicant's recitation of claims 1-4, 7, and 8.

Lastly with respect to claims 3 and 8, the claimed genus is made even larger with the recitation of "primers have one or more base substitutions, deletions, or insertions". Reading these claims as broadly as they are written, one could interpret that any primer sequence could meet this limitation as such a claimed genus requires no particular specific sequence, i.e., a primer sequence having every base pair substituted is encompassed by this claim. A review of the full content of the specification indicates that the sequence of SEQ ID NOS:1-6 and SEQ ID NOS: 7 and 8 and the primers made therefrom, are essential to the operation and function of the claimed invention. None of these primer sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons

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of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS:1-6 and SEQ ID NOS: 7 and 8, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process

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for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al.(US Patent 5,866,374: September 1999).

It should be noted that this art rejection is applied to claim 7 in light of its lacking clarity under 112 2nd paragraph(i.e., the claim does not require both primers in the same set).

Furthermore, with regard to claim 8, considering its current recitations of “primers have one or more base substitutions, deletions, or insertions”, any primer would anticipate the present claim requirements.

Kobayashi et al. teach a 42 base pair nucleic acid of SEQ ID NO:3 that shares 100% identity to applicant's SEQ ID NO: 7(see attached alignment)

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RESULT 3
AR031539
LOCUS AR031539 42 bp DNA linear PAT 29-SEP-1999
DEFINITION Sequence 3 from patent US 5866374.
ACCESSION AR031539
VERSION AR031539.1 GI:5945828
KEYWORDS
SOURCE Unknown.
ORGANISM Unknown.
Unclassified.
REFERENCE 1 (bases 1 to 42)
AUTHORS Kobayashi,O., Hayashi,N. and Sone,H.
TITLE Gene conferring flocculating property on yeast and gene product
thereof
JOURNAL Patent: US 5866374-A 3 02-FEB-1999;
FEATURES Location/Qualifiers
source 1..42
/organism="unknown"
/mol_type="unassigned DNA"
ORIGIN
Query Match 100.0%; Score 20; DB 6; Length 42;
Best Local Similarity 100.0%; Pred. No. 0.1;
Matches 20; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
QY 1 GGAATACTGCCTCTTGGAGT 20
|||
Db 20 GGAATACTGCCTCTTGGAGT 39
```

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748.

The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

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1/21/05

Jeffrey Fredman
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